HSE STATEMENT ON THE APPROVAL OF DOSIMETRY SERVICES

March 2020

Contents

HSE STATEMENT ON THE APPROVAL OF DOSIMETRY SERVICES

UNDER THE IONISING RADIATIONS REGULATIONS 2017

This Statement is intended to assist dosimetry services who may wish to be approved under regulation 36 of the Ionising Radiations Regulations 2017 (IRR17) for the purposes of IRR17 or regulation 18 of the Radiation (Emergency Preparedness and Public Information) Regulations 2019 (REPPIR). A general description of the administrative arrangements for making application is given and the subsequent processing of such applications by the Approval Body is outlined. Background notes on the requirements of the Regulations are given in Appendix I. The types of dosimetry service for which performance tests are required are listed in Section 7, and the pass/fail criteria applying to performance tests of dosimetry services are set out in Appendix II. The fees for approval are set out in the annual Health and Safety Fees Regulations. Those current for are set out in Appendix III.

1 Approval scheme for dosimetry services

1.1 General

1.1.1 The latest requirements for approval of dosimetry services (RADS) were published in 2020. Supplementary requirements for approval for the purposes of assessment and recording of emergency exposures under REPPIR were published in 2020 Unless otherwise indicated, all references in this Statement to RADS relate to the version issued in 2020 “Requirements for the approval of dosimetry services under the Ionising Radiations Regulations 2017”, or to the REPPIR supplement, which is subtitled “Supplement on approval for emergency exposures during intervention - the Radiation (Emergency Preparedness and Public Information) Regulations 2019.

1.2 Requirements for the approval of dosimetry services

1.2.1 In order to obtain approval under IRR17 and REPPIR19, a dosimetry service must be able to meet certain criteria specified by HSE. These criteria are set out in the RADS documents, as follows:

Requirements for the approval of dosimetry services under the Ionising Radiations Regulations 2017

- Part 1 - External Radiations
- Part 2 - Internal Radiations
- Part 3 - Co-ordination and record keeping
- Supplement on approval for emergency exposures during intervention

1.3 Approval Body

1.3.1 HSE is given power under regulation 36 of IRR17 to approve suitable dosimetry services, or to specify another Approval Body for this purpose. The Approval Body referred to in the RADS documents is HSE.

1.3.2 The Manager of the Approval Programme is:

Mr James Taylor
Radiation Team
Health & Safety Executive,
Redgrave Court,
Merton Road,
Bootle, Merseyside
L20 7HS
Tel: 07879 661820;
Email: james.taylor@hse.gov.uk

2 Application for approval

2.1 Approval Body

2.1.1 Initial application should be made to:

The Dosimetry Services Administrator,
Radiation Team
Health & Safety Executive,
Redgrave Court
Merton Road, Bootle, Merseyside
L20 7HS
Tel: 020 3028 4539);
Email: rad-admin@hse.gov.uk

2.2 Documentation to be submitted for application

2.2.1 The application should take the form of a letter or email from the head of the dosimetry service requesting approval or reassessment of approval. The letter/email should include the following points:

- a description of the type and size of service for which approval is sought and the particular radiations to be covered (for example, 'assessment of whole body dose from external x-ray, gamma and beta radiations') Where possible spectral information for the radiation(s) to be assessed should be included;
- where approval is sought for a service based on the use of personal dosemeters, the type and type number of dosemeter(s) that it is intended should be used;
- the full name and address of the dosimetry service (and contact details). Further details can be found in RADS 1 to 3 and the REPPIR supplement; and

- (if the service is to be limited to certain clients or groups of clients) the names of clients or a description of groups of clients.

In addition, the following should be sent with the application:

- a Statement of Service which gives the required details about the service;
- samples of outputs (with dummy data) and advice given to clients;
- a copy of a signed certificate for a successful performance test, where relevant (see Section 7); and
- the appropriate application fee (see Section 8.1 below).

2.2.2 Every application will be acknowledged and, if appropriate, the applicant will have an opportunity to have an exchange of views with an assessor appointed on behalf of HSE.

3 Assessment of dosimetry services

3.1 Criteria for approval

3.1.1 Dosimetry services will be assessed for compliance with the criteria for approval that have been specified by HSE in the RADS documents. They will also be expected to take account of the guidance set out in Section 9 below.

3.2 Method of assessment

3.2.1 HSE will assess applications for approval on the basis of:

- the Statement of Service provided by the applicant (taking into account any essential supporting documents);
- further information obtained during enquiries by HSE into the service's organisation, resources, personnel and methods (these enquiries will usually involve a visit by an assessor to follow up particular aspects; exceptionally, additional visits may be necessary); and
- reports of performance tests (see Section 7.1 below).

4 Reassessment of approved dosimetry services

4.1 Frequency of reassessment

4.1.1 Approval will be granted for an indefinite period of time. However, HSE may carry out a full or partial reassessment of the dosimetry service at any time. This will usually be when in its opinion the ADS is not acting in accordance with its statement of service or the performance of the ADS has or is suspected of having fallen below the required standards. If a reassessment is performed the ADS must pay the statutory fee.

4.2 Revocation of approval

4.2.1 HSE is empowered to revoke the approval of a dosimetry service which no longer meets the criteria. Details of the circumstances that could lead to revocation of approval

are given in the RADS documents. An approved dosimetry service will be invited to make representations to HSE before a final decision is taken to revoke an approval.

5 HSE Disputes procedure

5.1 HSE has a disputes procedure whereby anyone who is aggrieved by the actions or decisions of HSE staff may make representations to have the matter resolved at a higher level within HSE. If a dosimetry service is aggrieved during the assessment of the service, and wishes to pursue the matter, this should be taken up by writing to the individual member of staff's senior officer. The name of that officer appears on all correspondence sent out by HSE.

5.2 If it is recommended that approval should be withheld or revoked, or granted subject to certain conditions, HSE will write to the dosimetry service to warn them. Two weeks will be allowed to enable the dosimetry service to make representations, which will be considered on a fair and fresh basis before a decision is taken.

5.3 In the event of a decision by HSE to withhold approval or to revoke an approval previously granted, or to impose conditions on an approval, an aggrieved dosimetry service wishing to appeal against that decision should make representations to the Head of the Radiation Team together with full supporting documentary evidence. Such representations should be made within 3 months of receiving formal notice of the decision.

6 Performance tests

6.1 Types of dosimetry service required to undertake performance tests

6.1.1 The general requirements for performance tests are set out in the RADS documents. The types of dosimetry techniques for which performance tests are required are currently as follows:

- External radiation - whole body, gamma rays
- External radiation - whole body, fast neutrons
- External radiation - extremity/skin, gamma rays
- External radiation – lens of the eye
- External radiation - "special" accident dosimetry, whole body gamma rays (see paragraph 5 of RADS Part 1)
- Internal radiation - measurement of tritium in urine

7.1.2 The protocols for the tests are published separately by HSE: copies may be obtained from the Dosimetry Services Administrator.

7.2 Arrangements with test-house

7.2.1 Performance tests are required to be carried out either with a United Kingdom Accreditation Service (UKAS) accredited test-house, or, in certain cases, with a test-house nominated by HSE. Only in the case of performance tests for which no UKAS accredited test-house exists will HSE nominate a test-house. In the first instance, dosimetry services should therefore make enquiries of UKAS in order to identify a

suitable test-house. A list of laboratories which are accredited by UKAS for carrying out HSE published performance tests may be obtained by contacting UKAS (see https://www.ukas.com/contact/)

7.2.2 If a dosimetry service is seeking approval for one of the dosimetry techniques that are subject to performance testing requirements, it should make arrangements with an appropriate test-house for such a test to be undertaken within the 3 months prior to making an application (as set out in RADS Part 1 or Part 2 as appropriate). A copy of the results of that test should be included in the application. ADS are required to repeat these performance tests at least every 18 months and provide HSE with copies of the results of these tests also.

7.3 Results of performance tests

7.3.1 The results of performance tests are categorised as either Band A, Band B, or Band C. Band A represents a successful performance test, and new applicants for approval must achieve a Band A result before gaining approval. Band C (and in the case of approvals under REPPIR, Band B) represents a failed performance test; ADS who obtain such a result are required to take immediate action to review the reasons for such a result and develop an action plan to improve the service. A failed performance test may lead to revocation of approval (see Section 5.2 above). Band B (except for approvals under REPPIR) represents an intermediate case between success and failure. ADS obtaining Band B results must also carry out an in-service review; HSE will consider the outcome of such reviews at the time of any formal reassessment of approval.

7.3.2 For each of the types of performance test required, the definitions of Bands A, B and C are set out in Appendix II of this Statement.

8 Charges

8.1 Fees for approval

8.1.1 The current fees for approval of dosimetry services and for reassessment of approved dosimetry services are set out in the The Health and Safety and Nuclear (Fees) Regulations 2015 and may be found at www.legislation.gov.uk/uksi/2016/253/pdfs/uksi_20160253_en.pdf and in Appendix III of this Statement.

In line with HM Treasury guidance, the Health and Safety Commission decided that the full cost of the approval of dosimetry services for REPPIR purposes should be recovered from the beginning of April 2003. ‘Full cost’ means that all work carried out to maintain the approval programme (by the Programme Manager, Dosimetry Administrators and other HSE employees) must be recovered. Such maintenance requires significant amounts of work between assessments (for example, in relation to database maintenance, development work, dealing with queries and general management of the approvals programme). When this principle is applied to REPPIR, the flat rate fee at April 2015 was £1898

8.1.2 As of April 2015, the flat rate fee for the very similar work under IRR17 for groups

I, II and III was £806, well below full cost which means that the fees for REPPIR and IRR17 approvals will continue to differ significantly for some considerable time.

8.1.3 The Fees Regulations continue to provide for a fee to be charged to cover reasonable costs of travelling and subsistence of any member of HSE's staff in connection with an inspection of a dosimetry service. However, HSE will only make such a charge in the event of an inspection of a dosimetry service located outside the United Kingdom. The application fee now includes an element to cover the travelling and subsistence costs of inspections of dosimetry services located within the UK.

8.1.4 The applicant should include payment of the application fee at the time the application is made (see Section 3.1.1 above). Work on the approval or reassessments cannot start until the application fee is received.

8.1.5 HSE will invoice the applicant for the fees for the work carried out by the inspector and (if appropriate) for the travel and subsistence costs. These fees are payable before the results of the assessment are communicated to the applicant.

8.1.6 Where the Approval Body is in the process of considering an application for approval, or reassessment of approval, of a dosimetry service on the date that new Fees Regulations come into force, the fee charged for work done by an inspector will use the "old" hourly rate for work done prior to that date, and the "new" hourly rate for any further work. The administration fee will have been paid on application and will be the "old" fee.

9 Guidance for dosimetry services

9.1 HSE publications

9.1.1 In addition to the RADS documents, HSE has published the following guidance for dosimetry services:

a) General Guidance for Laboratories providing Personal Dosimetry Services, 1991 (reprinted, with minor amendments, 2001); and

b) Guidance on Individual Monitoring of Internal Radiation from the Prolonged Retention of Long-lived Radionuclides, (revised 1998).

These documents, which may be obtained from the Dosimetry Services Administrator (see Section 1.2), remain valid. Allowance will have to be made in using the latter document for references to IRR85 and old dose quantities.

9.2 Other publications

9.2.1 HSE also makes reference to other publications, which are listed in a bibliography in each of the RADS documents.

Supply of radiation passbooks for classified outside workers

Regulation 22(5) of IRR17 requires employers of classified outside workers (as defined) to provide them with a radiation passbook. These radiation passbooks are only obtainable through dosimetry services approved for co-ordination and record keeping

(ADS (Records)). ADS (Records) can obtain radiation passbooks from HSE Books. The address is:

HSE Books, PO Box 1999, Sudbury, Suffolk, CO10 2WA. Tel: 01787 881165; fax: 01787 313995; website: www.hsebooks.co.uk

11 Review of approval process

HSE will review the approval process from time to time to ensure that it is still relevant, consistent and transparent. We will consult dosimetry (and other relevant persons) regarding any changes we propose to make to the approval programme.

APPENDIX I

Background Notes on Legal Requirements

IRR17 came into force on 1st January 2018. Like the IRR99 it requires that employees who are likely to receive more than specified doses of ionising radiation be designated as classified persons. Regulation 22 of IRR17 requires employers of classified persons to make suitable arrangements with one or more approved dosimetry services for making systematic assessments of all doses likely to be significant and for making and maintaining dose records. The assessments of doses are required to be made by the use of suitable individual measurement for appropriate periods or, if this is inappropriate, by means of other suitable measurements.

- The employer's arrangements with an approved dosimetry service for keeping dose records must include:

- long term record keeping

- providing dose summaries, copies of dose records and termination records both to
- the employer and to HSE

- handling estimated doses and retaining the information on which the estimates are
- based

- providing radiation passbooks and maintaining records of doses for outside workers

HSE is given power under regulation 36 of IRR17 to approve suitable dosimetry services, or to specify another Approval Body for this purpose; currently the function remains with HSE. All dosimetry services wishing to be approved will need to apply to HSE as detailed in Section 3.1 of this Statement. Approvals are granted by means of a written certificate, which sets out the purposes for which approval is granted and the conditions to which that approval is made subject. They may be revoked in writing at any time. HSE may reassess any approval at any time.

Regulation 13, which deals with contingency plans, includes a requirement, in certain circumstances, for suitable dosemeters or other devices to be obtained from an approved dosimetry service, for the purpose of assessing doses received as a result of an accident. Regulation 24 sets out the dosimetry requirements which apply after an accident or other occurrence which is likely to cause a person to receive an effective dose exceeding 6 mSv or an equivalent dose greater than 15 mSv for the lens of an eye or greater than 150 mSv for the skin or the extremities. In approving dosimetry services, HSE issues certificates of approval which include these requirements, as well as the requirements of regulation 22. ADS require a separate HSE approval to provide an accident dosimetry service to employers who have to issue anyone with dosemeters or other devices under IRR17 regulation 13(2)(b), in circumstances where a dose to the whole body greater than 0.5Gy

might be received as a result of an accident, incident or occurrence as per L121 guidance on regulation 24 of the IRR17.

HSE maintains a current list of approved dosimetry services, which is updated at intervals which may be viewed on the HSE website at the following address: http://www.hse.gov.uk/radiation/ionising/doses/index.htm).

Further information may be obtained from “Work with Ionising Radiation”, Approved Code of Practice and guidance on IRR17, L121,

The Radiation (Emergency Preparedness and Public Information) Regulations 2019

If REPPIR19 applies to an employer they must make arrangements with dosimetry services approved under IRR17 for the purposes of REPPIR19 for assessment of doses received as a result of emergency exposures and for the separate recording of such doses in dose records.

APPENDIX II

Pass/fail criteria used in performance tests

The tables in this appendix show the definitions of the three bands into which results of performance tests are categorised. Table 1 is for the results of performance tests of external radiation dosimetry services measuring doses from gamma rays to the whole body; Table 2 is for dosimetry services measuring doses from fast neutron radiation to the whole body; Table 3 is for dosimetry services measuring doses to the (skin of the) extremities; Table 4 is for "special" accident dosimetry; and Table 5 is for measurements of tritium in urine.

The measurement protocols for the various performance tests, which define the terms "bias" and "relative standard deviation" used in the tables, are published by HSE. The Copies of the measurement protocols may be obtained from the Dosimetry Services Administrator (see Section 3.1).

TABLE 1 - External radiation - whole body gamma rays	
Band	**Definition**
Band A	The magnitude of the bias in the overall results is less than 20%; **and** the relative standard deviation in the overall results is less than 10%; **and** the magnitude of the bias for each of the groups of 5 dosemeters is less than 20% (30% for any group irradiated to 1.0 mSv or less); **and** the relative standard deviation for each of the groups of 5 dosemeters is less than 10% (15% for any group irradiated to 1.0 mSv or less)
Band B	The magnitude of the bias in the overall results is greater than or equal to 20% and less than 25%; **or** the relative standard deviation in the overall results is greater than or equal to 10% and less than 20%; **or** the magnitude of the bias for any of the groups of 5 dosemeters is greater than or equal to 20% (30% for any group irradiated to 1.0 mSv or less); **or** the relative standard deviation for any of the groups of 5 dosemeters is greater than or equal to 10% (15% for any group irradiated to 1.0 mSv or less)
Band C	The magnitude of the bias in the overall results is greater than or equal to 25%; **or** the relative standard deviation in the overall results is greater than or equal to 20%

APPENDIX II (CONTINUED)

TABLE 2 - External radiation - whole body fast neutrons	
Band	**Definition**
Band A	The magnitude of the bias in the overall results is less than 20%; **and** the relative standard deviation in the overall results is less than 25%; **and** the magnitude of the bias for each of the groups of 5 dosemeters is less than 20% (50% for any group irradiated to 1.0 mSv or less); **and** the relative standard deviation for each of the groups of 5 dosemeters is less than 25% (50% for any group irradiated to 1.0 mSv or less).
Band B	The magnitude of the bias in the overall results is greater than or equal to 20% and less than 30%; **or** the relative standard deviation in the overall results is greater than or equal to 25% and less than 30%; **or** the magnitude of the bias for any of the groups of 5 dosemeters is greater than or equal to 20% (50% for any group irradiated to 1.0 mSv or less); **or** the relative standard deviation for any of the groups of 5 dosemeters is greater than or equal to 25% (50% for any group irradiated to 1.0 mSv or less).
Band C	The magnitude of the bias in the overall results is greater than or equal to 30%; **or** the relative standard deviation in the overall results is greater than or equal to 30%.

APPENDIX II (CONTINUED)

TABLE 3 - External radiation - extremity/skin gamma rays	
Band	**Band Definition**
Band A	The magnitude of the bias in the overall results is less than 20%; **and** the relative standard deviation in the overall results is less than 15%; **and** the magnitude of the bias for each of the groups of 5 dosemeters is less than 20%; **and** the relative standard deviation for each of the groups of 5 dosemeters is less than 15%
Band B	The magnitude of the bias in the overall results is greater than or equal to 20% and less than 25%; **or** the relative standard deviation in the overall results is greater than or equal to 15% and less than 20%; **or** the magnitude of the bias for any of the groups of 5 dosemeters is greater than or equal to 20%; **or** the relative standard deviation for any of the groups of 5 dosemeters is greater than or equal to 15%
Band C	The magnitude of the bias in the overall results is greater than or equal to 25%; **or** the relative standard deviation in the overall results is greater than or equal to 20%

APPENDIX II (CONTINUED)

TABLE 4 - External radiation - accident dosimetry, whole body gamma rays	
Band	**Definition**
Band A	First report received by test house within 8 hours; **and** all dosemeters receiving a dose greater than 1 Gy correctly identified in the first report; **and** final report received by test house within 1 week; **and** all reported doses in final report within + 30% of "true" doses
Band B	As for Band A, except: **either** first report received by test house up to 1 hour late; **or** final report received by test house up to 1 day late; **or** 9 out of 10 reported doses in final report within + 30% of "true" doses
Band C	Any other result

APPENDIX II (CONTINUED)

TABLE 5 - Internal radiation - measurement of tritium in urine	
Band	**Definition**
Band A	The magnitude of the bias in the overall results is less than 15%; **and** the relative standard deviation in the overall results is less than 10%
Band B	The magnitude of the bias in the overall results is greater than or equal to 15% and less than 25%; **or** the relative standard deviation in the overall results is greater than or equal to 10% and less than 20%
Band C	The magnitude of the bias in the overall results is greater than or equal to 25%; **or** the relative standard deviation in the overall results is greater than or equal to 20%

APPENDIX III

Fees for for applications for approval or reassessment of approval of dosimetry services under IRR17 (see section 8 of the Statement)

1. Fees for applications for approval or reassessment of approval of dosimetry services under IRR17

Description	Fee	Fee for work by Nuclear or Specialist Inspector
Approval or reassessment of approval of Dosimetry Services granted under regulation 36 of the Ionising Radiations Regulations 2017		
Group I Dose record keeping		
(a) Where the application is solely in respect of Group I functions	£806	£136 per hour
(b) Where the application for Group I functions is linked to an application in respect of functions in another group	£806	£136 per hour
Group 2 External Dosimetry		
(a) Whole body (beta, gamma, thermal neutrons) film	£806	£136 per hour
(b) Whole body (beta, gamma, thermal neutrons) thermo-luminescent dosemeter (TLD)	£806	£136 per hour
(c) Whole body (neutron), other than sub-groups (a) or (b)	£806	£136 per hour
(d) Whole body, other than sub-groups (a), (b) or (c)	£806	£136 per hour
(d) Whole body, other than sub-groups (a), (b) or (c)	£806	£136 per hour
(e) Extremity monitoring	£806	£136 per hour
(f) Accident dosimetry, other than in the previous sub-groups	£806	£136 per hour
Group III Internal Dosimetry		
(a) Bio-assay, in vivo monitoring or air sampling	£806	£136 per hour
(b) for each additional one of the above techniques	£806	£136 per hour

2. Fees for applications for approval or reassessment of approval of dosimetry services under REPPIR

Description	Fee	Fee for work by Nuclear or Specialist Inspector
Purpose of application		
Approval or reassessment of approval of Dosimetry Services granted under regulation 36 of the Ionising Radiations Regulations 2017 for the purposes of regulation 18 of the Radiation (Emergency Preparedness and Public Information) Regulations 2019 (REPPIR)	**£1,898**	**£136**